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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,490	10/03/2003	Derek Lydiate	11089.0003.NPUS01	8191
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HOWREY LLP			ZHENG, LI	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/678,490	<b>Applicant(s)</b> LYDIATE ET AL.	
	<b>Examiner</b> LI ZHENG	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Applicant's cancellation of claim 11-13 and 15-29, and amendments to claims 1 and 14 filed on 11/29/2007 are acknowledged. As a result, claims 1-8, 10 and 14 are pending and examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejections of claims 1-8 and 10 under 35 U.S.C. 112, second paragraph, are withdrawn due to claim amendment.
4. The written description and enablement rejections of claims 1, 3, 5-18 under 35 U.S.C. 112, first paragraph, are withdrawn due to Applicants' argument.

***Claim Rejections - 35 USC § 102***

5. Claims 1-4 and 14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wilde et al., for the reasons of record stated in the Office action mailed May 30, 2007. Applicants traverse in the paper filed November 29, 2007. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that there is no hint or suggestion in Wilde et al. of a method of selection for a plant that comprises a coding region of interest using the lac operator-repressor system (response, the paragraph bridging pages 11-12). However, Wilde et al. teach every step of the claimed method and therefore anticipate the invention.

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Applicants further argue that hygromycin-resistance selection marker is not a coding region of interest in accordance with the present invention (response, page 12, 2<sup>nd</sup> paragraph). However, the specification clearly defines "coding region of interest" as any nucleotide sequence that is to be expressed within a plant cell, tissue or entire plant (response, page 12, 1<sup>st</sup> paragraph). Hygromycin-resistance selection marker gene of Wilde et al. clearly reads on such definition.

Applicants further argue that the reference does not teach the limitation that the selecting is done by identifying plants which have an identifiable genotype or phenotype of the dual transgenic plant associated with being deficient in the tag protein or deficient in expression of the first coding region (response, page 12, the 2<sup>nd</sup> paragraph from the bottom of the page). However, Wilde et al. teach that dual transgenic plants show reduced GUS activities, which is an identifiable phenotype for selection (Figure 8).

6. Claims 1-4 and 14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cigan et al., for the reasons of record stated in the Office action mailed May 30, 2007. Applicants traverse in the paper filed November 29, 2007. Applicants' arguments have been fully considered but were not found persuasive.

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Applicants argue that selection marker is not a coding region of interest in accordance with the present invention (response, page 13, last paragraph and page 14, 1<sup>st</sup> paragraph).

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However, the specification clearly defines “coding region of interest” as any nucleotide sequence that is to be expressed with a plant cell, tissue or entire plant (response, page 12, 1<sup>st</sup> paragraph).

Hgromycin-resistance selection marker gene of Wilde et al. clearly reads on such definition.

***Claim Rejections - 35 USC § 103***

7. Claims 1-8, 10 and 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al. in view of Mason et al. and Chou et al., for the reasons of record stated in the Office action mailed May 30, 2007. Applicants traverse in the paper filed November 29, 2007. Applicants’ arguments have been fully considered but were not found persuasive.

Applicants argue that there is no hint or suggestion that the new trait gene of Fabijanski et al. in locus 1 of Figure 3 is in operative association with the regulatory region which is separate to the regulatory region in operative association with the repressor 2 gene (response, page 15, 1<sup>st</sup> paragraph; also page 16, 2<sup>nd</sup> paragraph). However, according to the purpose of the invention of Fabijanski et al. (at least abstract), a new trait gene encompasses both promoter and a coding region conferring a new trait upon expression.

Applicants further argue that in Figure 3, locus 1, there is only regulatory region (Pro 1), which is operatively linked to the gene for the new trait, the lethal gene and the repressor 2 gene (response, page 16, 1<sup>st</sup> paragraph;). The Office does not agree with the interpretation of the Figure 3 of Fabijanski et al. Pro 1 in locus 1 only controls the expression of the lethal gene in combination with repressor binding site. New trait and repressor 2 gene are independent transcription units having their own promoters.

Applicants argue that throughout Fabijanski et al. it is taught that the gene for the novel trait is linked to the repressible lethal gene to ensure that the novel trait cannot persist in related species by transfer through sexual crossing, the arrangement of which is not found in present invention (response, page 16, 1<sup>st</sup> paragraph). However, ~~this~~ does not prevent the reference from being a reference for an obviousness prior art rejection.

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Applicants further argue that the method of Fabijanski et al. cannot operate (response, the paragraph bridging pages 16-17). The Office contends that the reason Applicants believe that the method does not work is due to the misinterpretation that repressor and lethal gene are controlled by the same promoter. Given the Offices' interpretation of Figure 3 as discussed above, the method of Fabijanski et al. is operable.

Applicants argue that there is no hint or suggestion in Mason et al. that the expression cassette comprising a gene encoding hepatitis B surface antigen linked to a CaMV 35 promoter would be used as a new trait in construct containing locus 1 of Fabijanski et al. (response, page 17, 2<sup>nd</sup> paragraph) and that at time that Fabijanski et al. presented their invention, construct of Manson et al. were well known, yet Fabijanski et al. do not include such constructs within their locus 1 construct. However, ~~the~~ motivation to combine the teaching of Fabijanski et al. with Mason et al. does not have to come from Mason et al. and that the rejection is an obviousness prior art rejection, therefore Fabijanski et al. do not have to teach the limitation as taught by Mason et al.

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Applicants further argue that the modified construct would not comprise a second regulatory region in operative association with the coding region of interest and a separate third regulatory region in operative association with the repressor gene. The Office contends that as

stated in previous office action, the new trait gene expression cassette is corresponding to second coding and regulatory regions and repressor 2 cassette is corresponding to both third coding and regulatory regions (note: the third regulatory region is NOT PRO 1 promoter as inadvertently indicated in previous office action). No limitation is missing from the modified construct because CaMV 35 promoter-hepatitis B surface antigen cassette is now corresponding to the second coding and regulatory regions and repressor 2 cassette is corresponding to both third coding and regulatory regions.

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Applicants further argue that even if a combination of Fabijanski et al. and Chou et al. is made, the resulting construct does not comprise a second regulatory region in operative association with the coding region of interest and a separate third regulatory region in operative association with the repressor gene (response, page 18 3<sup>rd</sup> paragraph). However, for the same reasons discussed above, no limitation is missing from the modified construct because the new trait gene expression cassette is corresponding to second coding and regulatory regions and repressor 2 cassette is corresponding to both third coding and regulatory regions.

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### ***Double Patenting***

8. Claims 1-8, 10 and 14 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-24 of copending Application No. 10/719,996 in view Mason et al.

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Applicants wish to postpone the response to this rejection until the claims are otherwise allowable (page 19, 2<sup>nd</sup> paragraph). Therefore the rejection is maintained.

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9. Claims 1-8, 10 and 14 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 21 and 24 of copending Application No. 10/995,951 in view Mason et al.

Applicants wish to postpone the response to this rejection until the claims are otherwise allowable (page 19, 4<sup>th</sup> paragraph). Therefore the rejection is maintained.

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### **Summary**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ashwin Mehta/

Primary Examiner, Art Unit 1638